2025-2026 Respiratory Season Immunization Updates and Recommendations

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Disclosures

I have nothing to disclose concerning possible financial relationships with ineligible companies that may have a direct or indirect interest in the subject matter of this presentation.

Objectives

- Describe the influenza vaccination recommendations for the upcoming season;
- Describe the recommendations for COVID-19 vaccination;
- Describe the RSV prevention products that are available and understand their recommendations for use

Make-up of 25/26 influenza vaccines

- No confirmed detections of wild-type influenza B/Yamagata lineage viruses in global surveillance since March 2020
- All influenza vaccines available in the United States during the 2025–26 season will be trivalent vaccines
- Most will be single dose and not contain thimerosol

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Depending on Source 25/26

U.S. egg-based influenza vaccines

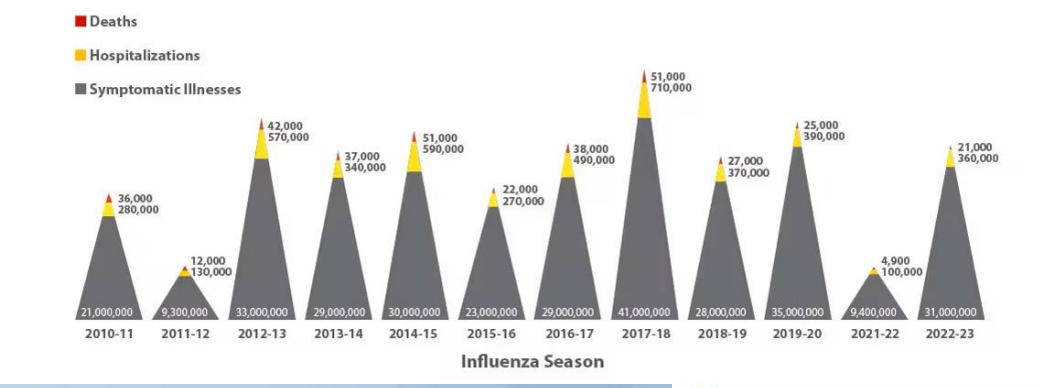
- An influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus
- An influenza A/Croatia/10136RV/2023 (H3N2)-like virus
- An influenza B/Austria/1359417/2021 (Victoria lineage)-like virus

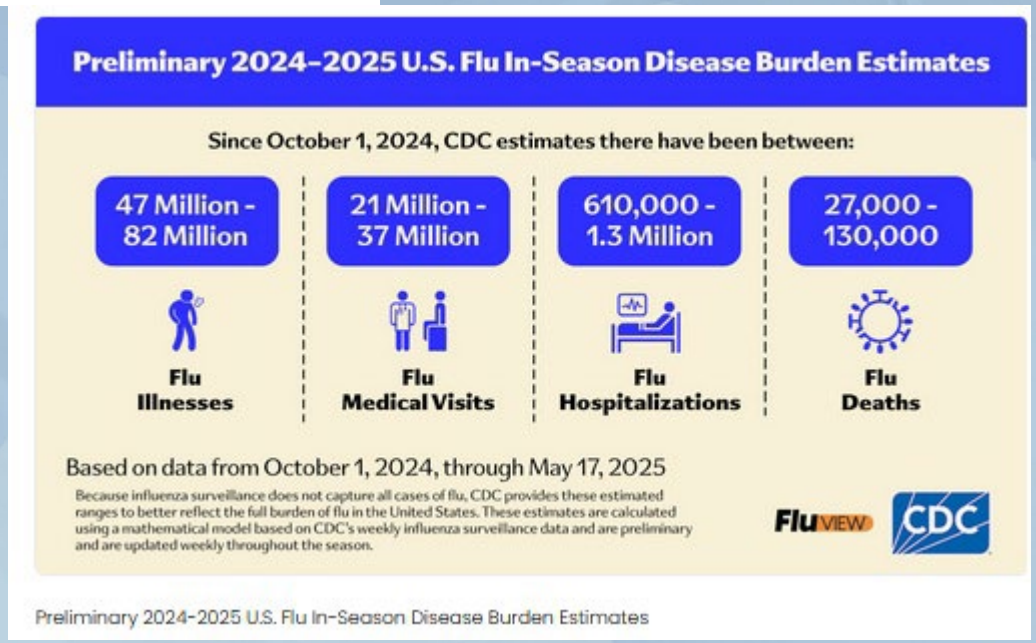
U.S. cell culture-based (ccIIV3) & recombinant (RIV3)

- an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus
- An influenza A/District of Columbia/27/2023 (H3N2)-like virus
- An influenza B/Austria/1359417/2021 (Victoria lineage)-like virus

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Flu Burden





Preliminary 2024-2025 U.S. Flu In-Season Disease Burden Estimates

Estimated U.S. Flu Burden, By Season CDC

Who is at greatest risk from influenza?

- Children under 5 years, but especially those under age 2
- Adults 65 years and older
- Pregnant people
- non-Hispanic Black persons, Hispanic or Latino persons, and American Indian or Alaska Native personsResidents of nursing homes or other long-term care facilities
- Medical conditions that increase a person's risk of severe influenza include: chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)
- Immunocompromising conditions due to any cause (including, but not limited to, immune suppression caused by medications or HIV);
- Extreme obesity (body mass index of 40 or greater for adults);
- Chronic use of aspirin- or salicylate-containing medications in children through age 18 (due to the risk of Reye syndrome after influenza infection)
- People who live in nursing homes and other long-term care facilities

https://www.cdc.gov/flu/highrisk/index.htm

Who is recommended to get vaccinated against influenza?

- ACIP/CDC recommends annual vaccination for all people ages 6 months and older who do not have a contraindication to influenza vaccination
- Children aged ≤18 years, pregnant women, and all adults should receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

What influenza vaccines products are available for the 25/26 season?

Influenza Vaccine Products for the 2025–2026 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	CVX Code	Vaccine Product Billing Code[2] CPT
AstraZeneca	FluMist (LAIV3)	0.2 mL (single-use nasal spray)	0	2 through 49 years	111	90660
					333*	NA*
GSK	Fluarix (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
	FluLaval (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
Sanofi	Flublok (RIV3)	0.5 mL (single-dose syringe)	0	9 years & older	155	90673
	Fluzone (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
		0.5 mL (single-dose vial)	0	6 months & older[3]	140	90656
		5.0 mL multi-dose vial (0.25 mL dose)	25[4]	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	25[4]	6 months & older	141	90658
	Fluzone High-Dose (HD-IIV3)	0.5 mL (single-dose syringe)	0	65 years & older[5]	135	90662
CSL Seqirus	Afluria (IIV3)	5.0 mL multi-dose vial (0.25 mL dose)	24.5[4]	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	24.5[4]	3 years & older[6]	141	90658
		0.5 mL (single-dose syringe)	0	3 years & older[3]	140	90656
	Fluad (aIIV3)	0.5 mL (single-dose syringe)	0	65 years & older[5]	168	90653
	Flucelvax (ccIIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	153	90661
		5.0 mL multi-dose vial (0.5 mL dose)	25[4]	6 months & older[3]	320	90661

* Self- or caregiver-administered at home

NOTES

1. All 2025–2026 seasonal influenza vaccines are trivalent. IIV = egg-based inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV); RIV = recombinant hemagglutinin influenza vaccine (injectable); aIIV = adjuvanted inactivated influenza vaccine.
2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.
3. Dosing for infants and children age 6 through 35 months:
   - Afluria 0.25 mL
   - Fluarix 0.5 mL
   - Flucelvax 0.5 mL
   - FluLaval 0.5 mL
   - Fluzone 0.25 mL or 0.5 mL
4. In June 2025, ACIP voted to no longer recommend use of inactivated influenza multi-dose vials (MDV) containing thimerosal as a preservative. Availability of MDV formulations varies by manufacturer. As of August 4, 2025, CDC's website states that there is no evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site.
5. Solid organ transplant recipients age 18 through 64 years who are on immunosuppression medication regimens may receive either high-dose IIV (HD-IIV) or adjuvanted IIV (aIIV) influenza vaccine as options for influenza vaccination, without a preference over other age-appropriate IIVs or RIVs.
6. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p4072.pdf
Item #P4072 (8/5/2025)
Scan for PDF

https://www.immunize.org/wp-content/uploads/catg.d/p4072.pdf

Who should get what flu vaccine?

- Age 6 month to 64 years CDC recommends any available age-appropriate influenza vaccine product
- Age 65 years and older CDC preferentially recommends:
  - Fluzone High-Dose (HD-IIV, Sanofi), Flublok recombinant (RIV, Sanofi), and Fluad adjuvanted (aIIV, CSL Seqirus)
- Solid organ transplant recipients (SOTRs) age 18 years through 64 years have the option of receiving HD-IIV or aIIV, both of which are licensed for people age 65 years or older, however, not preferential
- LAIV3 (Flumist)is not recommended during pregnancy, for immunocompromised persons, for persons with certain medical conditions, or for persons who are receiving, have recently received, or are about to receive influenza antiviral medications. LAIV3 should not be administered to persons aged <2 or >49 years

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

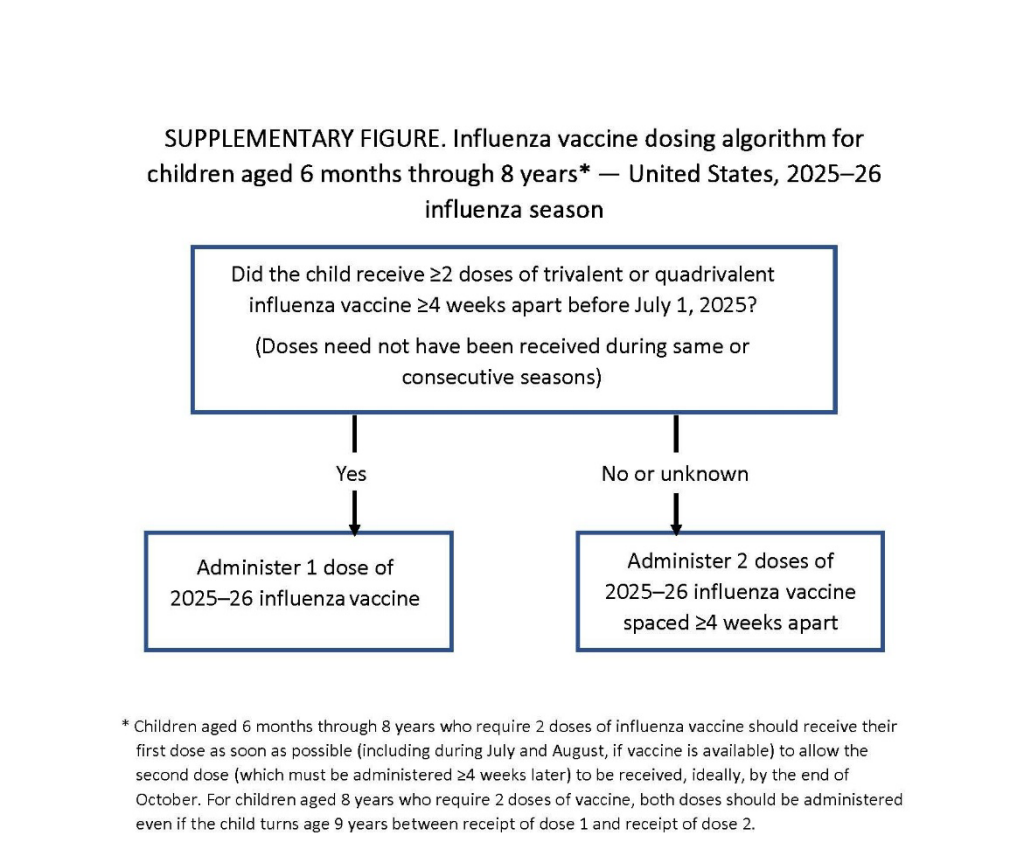
When should flu vaccination be offered?

- Most groups should be offered vaccination in September and October and continue vaccinating as long as influenza is circulating
- Specific groups to consider:
  - Most adults and pregnant persons in 1st/2nd trimester, avoid immunization in July/August unless later vaccination might not be possible
  - Children 6 months – 8 years who need 2 doses can be vaccinated as soon as a dose is available
  - Pregnant in 3rd trimester can be vaccinated in July/August

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Who needs 2 doses of influenza vaccine?

- Persons aged 9 years and over only need one dose.
- Determine the number of needed doses based on the child's age at the time of the first dose and the number of doses of influenza vaccine received in previous seasons.



https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Persons with Egg Allergies

- Studies indicate that egg-allergic persons are NOT at increased risk of severe allergic reaction to egg-based influenza vaccines
- Therefore, any age-appropriate influenza vaccine can be used for a person with an egg allergy
- No additional safety measures are recommended as all vaccines should be administered in settings which have appropriate personnel and equipment to handle rapid recognition and treatment of acute allergic reactions

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Flu vaccine and travelers

- All travelers should ensure vaccination at least 2 or more weeks prior to departure
- Travel to Southern hemisphere may not be covered by Northern hemisphere flu vaccine and the southern hemisphere vaccine may not be available in U.S.

https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm

Contraindications/Precautions for Specific Flu Vaccines

Influenza Vaccine Contraindications and Precautions	
Egg-based IIV3	C: History of severe reaction (anaphylaxis) to any influenza vax P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine
ccIIV3	C: History of severe reaction (anaphylaxis) to ccIIV of any valency or vax component P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; History of severe reaction (anaphylaxis) to any influenza vax
RIV3	C: History of severe reaction (anaphylaxis) to RIV of any valency or vax component P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; History of severe reaction (anaphylaxis) to any influenza vax
LAIV3	History of severe reaction (anaphylaxis) to any flu vax; concomitant aspirin of salicylate in children or adolescents; children 2-4 yrs with asthma; children or adults who are immunocompromised; close contacts of severely immunocompromised; persons with active communication with CSF & the oropharynx, nasopharynx or any other CSF leak; Persons with cochlear implants; Receipt of antiviral medication within the previous 48 hours (oseltamivir/zanamivir) or 5 days (peramivir) 17 days (baloxavir) P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; Asthma in person≥ 5 years; other medical condition that could predispose complications from influenza

C=Contraindication P=Precaution GBS= Guillain-Barre syndrome

https://www.cdc.gov/flu/media/pdfs/2024/08/acip-2024-25-summary-of-recommendations.pdf

COVID-19 25/26 Vaccines

COVID-19 2025/2026

- Three products were approved for the 2025/2026 season
- mRNA vaccines
  - Moderna-Spikevax:
  - 65 years of age and older, or
  - 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

  - Moderna-mNEXSPIKE:
  - 65 years of age and older, or
  - 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

  - Pfizer-Comirnaty:
  - 65 years of age and older, or
  - 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
- Protein subunit vaccine
  - 65 years of age and older, or
  - 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

Composition of COVID-19 25/26 vaccines

- A monovalent JN.1-lineage vaccine composition. Following the vote, the committee discussed considerations for the selection of JN.1 and/or a specific JN.1-lineage strain for COVID-19 vaccines (2025-2026 Formula)

Pfizer BioNTech COVID-19 2025/2026 Vaccine

- How Supplied:
  - Adult: 12 + Product For individuals 12 years of age and older: a single dose is 0.3 mL supplied in prefilled syringes labeled with gray borders
    - If prefilled syringe has been frozen, discard.
    - Remove tip cap by slowly turning the cap counterclockwise while holding the Luer lock and attach a sterile needle. Use immediately. If COMIRNATY cannot be used immediately, it must be used within 4 hours.
  - 5-11 years: For individuals 5 years through 11 years of age: a single dose is 0.3 mL supplied in vials with blue caps and labeled with blue borders.
    - If vial is frozen, thaw vial in the refrigerator [2ºC to 8ºC (35ºF to 46ºF) for up to 2 hours] or at room temperature [up to 25ºC (77ºF) for 30 minutes]
    - Prior to use, mix by inverting vial gently 10 times. Do not shake.
    - Withdraw a single 0.3 mL dose using a sterile needle and syringe.

https://labeling.pfizer.com/ShowLabeling.aspx?id=16351&format=pdf

Moderna COVID-19 2025-2026 Vaccine

- How supplied:
- Storage:
  - Store frozen between -50°C to -15°C (-58°F to 5°F).
  - After thawing, SPIKEVAX may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up
  - to 60 days or up to the expiration date printed on the carton, whichever comes first.
  - After thawing, SPIKEVAX may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours. No reconstitution

Spikevax® (COVID-19 VACCINE, mRNA) 2026-2025 Formula Prescribing Information available at https://www.modernatx.com/en-US/products/spikevax

NUVAXOVID COVID-19 2025/2026

- Fully approved
- Administer the 0.5 mL dose of Novavax COVID-19 Vaccine, Adjuvanted intramuscularly
- Similar Side effects to mRNA; Evidence of GBS
- NUVAXOVID is supplied as a pre-filled syringe (NDC 80631-207-01) containing 1 dose of 0.5 mL. Ten pre-filled syringes are supplied in a carton (NDC 80631-207-10).
- Store in the original carton to protect from light.
- Store in a refrigerator at 2°C to 8°C (36°F to 46°F)

file:///C:/Users/Krista%20Capehart/Downloads/Package-Insert-and-Patient-Package-Insert-NUVAXOVID%20(1).pdf

FDA approved indications

- Moderna-Spikevax®:
- 65 years of age and older, or
- 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
- Administer dosage according to the Prescribing Information.

Age	SPIKEVAX Dosing Regimen, Dose and Schedule
2 years through 11 years	Single dose, 0.25 mL
12 years and older	Single dose, 0.5 mL
If previously vaccinated with any COVID-19 vaccine, administer the dose ≥2 months after the last dose of COVID-19 vaccine	

Individuals 6 Months Through 23 Months of Age by Number of Previous Doses of Moderna COVID-19 Vaccine Received (2.3)

Number of Previous Doses of Moderna COVID-19 Vaccine(s)[a]	SPIKEVAX Dosing Regimen, Dose and Schedule
0[b]	2 doses,[c] 0.25 mL each Dose 1: month 0 Dose 2: month 1
1	Single Dose, 0.25 mL One month after receipt of a previous dose of Moderna COVID-19 vaccine[a]
≥2	Single dose, 0.25 mL ≥2 months after receipt of the last previous dose of Moderna COVID-19 vaccine[a]

[a] Previous dose refers to a dose of any authorized Moderna COVID-19 Vaccine.
[b] Not previously vaccinated with any COVID-19 vaccine.
[c] Individuals turning from 23 months to 2 years of age during the vaccination series should receive both doses with SPIKEVAX.

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Moderna-mNEXSPIKE®:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
- Administer dosage according to the Prescribing Information. Administer MNEXSPIKE as a single 0.2 mL dose intramuscularly. Administer at least 3 months after the last dose of COVID-19 vaccine if previously vaccinated.

mNEXSPIKE® (COVID-19 Vaccine, mRNA) injectable suspension, for intramuscular use 2025-2026 Formula Prescribing Information available at https://products.modernatx.com/mnexspike

Pfizer-Comirnaty®:

- 65 years of age and older, or
- 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
- Administer dosage according to the Prescribing Information. Administer COMIRNATY® as a single 0.3 mL dose intramuscularly. Administer at least 2 months after the last dose of COVID-19 vaccine if previously vaccinated.

COMIRNATY® (COVID-19 Vaccine, mRNA) injectable suspension, for intramuscular use 2025-2026 Formula Available at https://www.pfizer.com/products/product-detail/comirnaty

Novavax-NUVAXOVID:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
- Administer dosage according to the Prescribing Information. Administer NUVAXOVIX® a single 0.5 mL dose intramuscularly. For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of NUVAXOVID at least 2 months after the last dose of COVID-19 vaccine.

NUVAXOVID (COVID-19 Vaccine, Adjuvanted) injectable suspension, for Intramuscular use 2025-2026 Formula Available at https://www.fda.gov/vaccines-blood-biologics/vaccines/nuvaxovid

What are risk factors??

- >65 Years
- Medical complexity
- Genetic, neurologic, or metabolic conditions
- Congenital heart disease
- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Chronic lung disease
- SUD
- TB
- Cystic Fibrosis
- Dementia
- Diabetes
- Disabilities
- Heart conditions
- Hemoglobin disorders
- HIV
- Immunologic disorders
- Mental health disorders
- Overweight and obesity
- Physical inactivity
- Pregnancy
- Smoking
- Solid organ or stem cell transplant

https://www.cdc.gov/covid/risk-factors/index.html

American Association of Pediatrics COVID-19 Recommendations

- Infants and children 6 through 23 months of age are at high risk for severe COVID-19. 2-4 The AAP recommends all infants and children in this age group who do not have contraindications* receive 2025-2026 COVID-19 vaccine, as follows:
  - Those who are previously unvaccinated should receive an initial vaccine series.
  - Those who are previously vaccinated but did not complete their initial vaccine series should complete their initial vaccine series
  - Those who are previously vaccinated and completed their initial series should receive a single dose. This dose should be administered at least 8 weeks after the last dose was received.
  - Those with a previous asymptomatic infection or symptomatic disease caused by SARS- CoV-2 should also receive COVID-19 vaccination.

https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infantshttps://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infants

American Association of Pediatrics COVID-19 Recommendations

- Children 6 months through 18 years of age who are moderately or severely immunocompromised require 2 or more doses of age-appropriate 2025-2026 COVID-19 vaccine depending on previous vaccination status
- The AAP recommends a single dose of age-appropriate 2025-2026 COVID-19 vaccine for all children and adolescents 2 through 18 years of age in the following risk groups regardless of prior COVID-19 vaccination status:
  - Persons at high risk of severe COVID-19
  - Residents of long-term care facilities or other congregate settings
  - Persons who have never been vaccinated against COVID-19
  - Persons whose household contacts are at high risk for severe COVID-19

https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infantshttps://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infants

American Association of Pediatrics COVID-19 Recommendations

- Children 2 through 18 years of age not included in the risk groups above whose parent or guardian desires their protection from COVID-19 should be offered a single dose of age- appropriate 2025-2026 COVID-19 vaccine. This dose should be administered at least 8 weeks after the last dose was received.
- Any available COVID-19 vaccine appropriate by age and health status that is approved by the US Food and Drug Administration through a biologics license application or authorized through emergency use authorization can be used. The most updated version of the COVID-19 vaccine that is available should be used.

https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infantshttps://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infants

American College of Obstetrics and Gynecology

- All pregnant and lactating individuals receive an updated COVID-19 vaccine or “booster.” All clinicians should provide a strong recommendation for updated COVID-19 vaccination to their pregnant and lactating patients.
- Infants aged less than 6 months are at increased risk for severe COVID-19 disease but are not yet eligible for COVID-19 vaccination, and they depend on transplacental transfer of maternal antibodies for protection.
- COVID-19 vaccine safety during pregnancy has been well established
- Vaccination may occur in any trimester, and emphasis should be on vaccine receipt at the earliest opportunity to maximize maternal and fetal health
- COVID-19 vaccines may be administered simultaneously with other vaccines. This includes vaccines routinely recommended during pregnancy, such as influenza, respiratory syncytial virus (RSV), and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)

Multiple Vaccine Administration

- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
  - Coadministration of COVID-19 and RSV vaccine for older adults
  - There are additional considerations if administering an orthopoxvirus vaccine and COVID-19 vaccine
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age.
  - Separate injection sites by 1 inch or more.
  - For older children (≥11 years), the deltoid muscle can be used.
  - For younger children, if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Considerations for Revaccination

- Recipients of HCT or CAR-T-cell therapy \
- Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies
- Case by case basis for those with on-going immunocompromising therapy

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Expected Adverse Effects Covid-19 Vaccines

It is recommended that everyone ages 6 months and older stays up-to-date on COVID-19 vaccination

Anticipated side effects (children, adolescents, and adults):

- Local: pain, swelling, erythema at the injection site
- Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

- Younger children (6 months to 5 years):
  - Local: pain, tenderness at the injection site
  - Systemic: fatigue, irritability/crying and drowsiness/sleepiness

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf
https://www.fda.gov/media/151707/download?attachment

Adverse Effects

- Myocarditis/Pericarditis
  - Seen most frequently in males ages 12-39 years within 7 days after receiving the 2nd dose
  - Risk estimates of myocarditis/pericarditis in 18–39-year-olds during days 0-7 after 2 doses were modestly higher after Moderna than after Pfizer
- Guillain-Barre After COVID-19 Vaccination
  - No evidence of association between GBS and mRNA-based COVID-19 vaccines
  - Findings were consistent with an association between increased risk of GBS and Janssen COVID-19 vaccine

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/07-COVID-Klein-508.pdf

Respiratory Syncytial Virus(RSV) Vaccines

Who is most at risk for RSV?

- Very young and the very old (esp over 75 years)
- Risk also increases in those with one or more chronic health conditions, including people who are moderately or severely immunocompromised and people who are considered frail or who live in a nursing home or long-term care facility
- Older adults: U.S. adults age 65 and older, RSV is responsible for approximately 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths each year
- Infants: 50,000–80,000 RSV-associated hospitalizations and 100–300 RSV-associated deaths occur each year among U.S. infants and children younger than age 5 years. Some otherwise healthy American Indian or Alaska Native (AI/AN) children experience higher rates of severe RSV disease

https://www.immunize.org/vaccines/a-z/rsv/

3 Current RSV Vaccines Approved in US

- All 3 have indication for prevention of RSV-associated lower respiratory tract disease (LRTD) in adults 60 and older plus 18 through 59 years of age who are at increased risk for LRTD caused by RSV
  - RSVPreF3 (Arexvy®, GSK) – recombinant protein vaccine
  - RSVpreF (Abrysvo®, Pfizer) - recombinant protein vaccine
    - licensed for use during pregnancy (during 32 through 36 weeks and 6 days' gestation) September through January; currently only initial pregnancy not upon repeated pregnancy
  - mRNA RSV (mResvia®, Moderna)

https://labeling.pfizer.com/ShowLabeling.aspx?id=19589
https://static.modernatx.com/pm/6cef78f8-8dad-4fc9-83d5-d2fbb7cff867/36130c97-6fb0-4bea-9f2e-fb5be7a90729/36130c97-6fb0-4bea-9f2e-fb5be7a90729_viewable_rendition__v.pdf
https://labeling.pfizer.com/ShowLabeling.aspx?id=19589

RSVPreF3 (Arexvy, GSK)

- A single-dose vial of lyophilized antigen component (powder) and a single-dose vial of adjuvant suspension component, includes an AS01adjuvant, (liquid)
- Must be reconstituted
- Before reconstitution: Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F) in original packaging
- Administer immediately or store in the refrigerator between 2°C and 8°C (36°F to 46°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours prior to use.

RSVpreF vaccine (Abrysvo, Pfizer)

- consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes)
- a single-dose vial of 120 µg of lyophilized preF antigen component (60 µg from RSV-A, 60 µg from RSV-B) to be reconstituted with the accompanying vial of sterile water diluent component
- Pfizer's vaccine is supplied in a kit with three components:
  - Vial of Lyophilized Antigen Component (a sterile white powder)
  - Prefilled syringe containing Sterile Water Diluent Component
  - Vial adapter: Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – ABRYSVO (fda.gov)
- Before reconstitution: Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F) in original packaging
- After reconstitution: Immediately administer the vaccine; you should prepare the vaccine only when ready for use. If you do not immediately administer the vaccine, there are some minor differences in storage: Store the reconstituted vaccine ONLY at room temperature (15°C to 30°C / 59°F to 86°F).Do NOT refrigerate.
- Once you've reconstituted the vaccine, you have 4 hours to use the vaccine before it must be discarded

Healthcare Providers: RSV Vaccination for Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html#:~:text=CDC%20recommends%20one%20dose%20of,32%20through%2036%20weeks%20pregnant.

RSVpreF vaccine (Abrysvo, Pfizer)

- Administration: intramuscular injection in the deltoid
- Sufficient evidence does not exist at this time to determine the need for additional doses in subsequent pregnancies.
- Pregnant people can receive RSV, Tdap, COVID-19, and influenza vaccines at the same clinic visit when the vaccines are recommended.
- Contraindication: history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine
- Precaution: Moderate or severe acute illness, with or without fever, vaccination should generally be deferred until the patient improves

Healthcare Providers: RSV Vaccination for Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html#:~:text=CDC%20recommends%20one%20dose%20of,32%20through%2036%20weeks%20pregnant.

Efficacy of RSVpreF vaccine (Abrysvo, Pfizer)

- Maternal RSV vaccine:
  - Vaccine efficacy following season one was 88.9% (95.0% CI: 53.6%, 98.7%)
  - Efficacy against RSV-associated lower respiratory tract disease (LRTD), defined by three or more symptoms, after disease surveillance in season two was 77.8% (95.0% CI: 51.4, 91.1)
  - Vaccine efficacy against RSV-associated LRTD (RSV A and RSV B), defined by three or more symptoms, across both seasons after approximately 16.4 months of disease surveillance was 81.5% (95.0% CI: 63.3, 91.6)

Walsh EE, Gonzalo PM, et al. "Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults." The New England Journal of Medicine. April 20, 2023.
https://www.nejm.org/doi/full/10.1056/NEJMoa2213836?query=featured_home

mResvia (mRNA RSV vaccine)

- Comes as a prefilled syringe with frozen suspension to be thawed prior to administration
- contains mRNA that encodes the prefusion form of the RSV F glycoprotein
- Frozen Storage Store frozen between -40°C to -15°C (-40°F to 5°F).

- Storage after Thawing Storage at 2°C to 8°C (36°F to 46°F):
  - Pre-filled plastic syringes may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to use. Storage at 8°C to 25°C (46°F to 77°F):
  - Pre-filled plastic syringes may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time. Syringes should not be returned to the refrigerator after being thawed at room temperature.
- Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.
- Do not refreeze once thawed. Do not shake.

https://static.modernatx.com/pm/6cef78f8-8dad-4fc9-83d5-d2fbb7cff867/36130c97-6fb0-4bea-9f2e-fb5be7a90729/36130c97-6fb0-4bea-9f2e-fb5be7a90729_viewable_rendition__v.pdf

Recommendations for RSV Vaccine (New recommendation from last season)

- Single dose of any of the three licensed RSV vaccines for all adults aged 75 years and older
- Single dose of any RSV vaccine for adults aged **50** through 74 years who are increased risk for serious RSV infection due to specific high-risk conditions, frailty, or high-risk living arrangements

https://www.cdc.gov/vaccines/acip/recommendations.html

Who are those in the 50–74-year-old category at increased risk?

- Chronic heart, lung, kidney, and liver disease, diabetes, severe obesity, neurologic and neuromuscular conditions which impair the airway clearance and chronic blood disorders
- Moderate or severe immune compromise
- Overall frailty
- Residence in a nursing home or other long-term care facility
- Other chronic medical conditions or risk factors not specified in this list that a healthcare provider determines might increase the risk of severe disease due to RSV respiratory infection

- People age 60 through 74 years who do not have a medical condition or risk factor that increases their risk of severe RSV disease are not recommended to receive RSV vaccine: they should wait to be vaccinated until a high-risk condition develops or until they turn 75, whichever comes first

https://www.immunize.org/ask-experts/what-conditions-put-older-people-at-the-highest-risk-of-complications-of-rsv/

How long will the RSV vaccine provide protection?

- Currently only one dose of the RSV vaccine is recommended currently. If vaccinated last year, should not receive another dose.
- Continuing to monitor for continual efficacy

https://www.immunize.org/ask-experts/topic/rsv/
https://www.cdc.gov/vaccines/acip/recommendations.html

RSV vaccines Abrysvo (Pfizer) and Arexvy (Glaxo)

- January 7, 2025
- Post marketing observational studies demonstrated increased risk of Guillain-Barré syndrome (GBS) during the 42 days following vaccination with both Abrysvo and Arexvy

Nirsevimab-monoclonal antibody

- Injectable, long-acting monoclonal antibody product that gives the recipient direct, immediate protection through passive immunization
- Should NOT be called a vaccine. Can lead to medication errors.
- ACIP recommends one dose of nirsevimab (Beyfortus, Sanofi) preventive antibody for *all* infants less than 8 months and 0 days of age who are born during or are entering their first RSV season. However, if the mother was vaccinated with RSV vaccine, usually not necessary except in limited circumstances and a Risk-based immunization of children age 8 months through 19 months entering their second RSV season for those with high-risk criteria

Clesrovimab-monoclonal antibody

- No preference between nirsevimab and clesrobimab → one or the other!
- Injectable, long-acting monoclonal antibody product that gives the recipient direct, immediate protection through passive immunization
- Should NOT be called a vaccine. Can lead to medication errors.
- ACIP recommends one dose of clesrovimab preventive antibody for *all* infants less than 8 months and 0 days of age who are born during or are entering their first RSV season. However, if the mother was vaccinated with RSV vaccine, usually not necessary except in limited circumstances and a
- Does NOT have the second season indication
- Dose is the same regardless of weight (105mg pre-filled syringe) intramuscular

RSV protection

Choose One Product to Prevent Severe RSV Disease in Infants

Maternal RSV vaccination
- Pfizer Abrysvo

- or -

Infant RSV antibody
- Nirsevimab
- Clesrovimab*

https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/03-jones-maternal-peds-rsv-508.pdf49

Pneumococcal Vaccine Update

Capvaxive (PCV21)

- Approved by FDA 6/17/24
- Indication for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) in ages 18 years and up

Not just one more serotype covered!

Adult Pneumococcal Vaccines

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	15A	15C	16F	23A	23B	24F	31	35B
PCV15																																
PCV20																																
PPSV23																																
PCV21																																

21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck):

- **Approved by the FDA for adults aged ≥18 years on June 17, 2024[1]**

PCV13=13-valent pneumococcal conjugate vaccine
PCV15=15-valent pneumococcal conjugate vaccine
PCV20=20-valent pneumococcal conjugate vaccine
PPSV23=23-valent pneumococcal polysaccharide vaccine

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/01-Pneumococcal-Loehr-508.pdf

CDC Recommendation Update

- ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/01-Pneumococcal-Loehr-508.pdf

ACIP October 2024 Meeting/CDC Endorsement

- Advisory Committee on Immunization Practices voted to lower the age for pneumococcal vaccination from 65 to 50 years old
- Permits more adults to protect themselves from invasive pneumococcal disease
- CDC recommends **PCV15, PCV20, or PCV21** for adults who never received a PCV and are
- Ages 50 years or older
- Ages 19 through 49 years with certain chronic conditions and other factors
- If PCV15 is used, it should be followed by a dose of **PPSV23**.
- Check out the PneumoRecs app

https://www.cdc.gov/pneumococcal/causes/index.html#cdc_causes_risk-risk-factors

Serotype 4

- In certain adult populations in the Western United States with data (Alaska, Colorado, New Mexico, Navajo Nation,1 and Oregon), serotype 4 has caused high percentages (i.e., ≥30%) of invasive pneumococcal disease (IPD). CDC currently doesn't know if this is seen in other parts of the Western United States that don't routinely monitor IPD data.
- Economic models looked at what happens if the proportion of pneumococcal disease cases caused by serotype 4 is **at least 30%**. In those models, PCV21 use compared with PCV20 use could
- Be more expensive
- Result in more deaths from IPD in some cases
- When serotype 4 was **less than 30%** in these models, PCV21 could be less expensive and save more lives than PCV20 in some cases. These models didn’t evaluate PCV15 and PPSV23 use.

https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/risk-indications.html

Summary

- All patients 6months + recommended to get the trivalent influenza vaccine unless specific contraindication.
- COVID-19 vaccines are now available with the 25/26 variant and are monovalent, but access is limited due no CDC recommendations etc
- RSV is recommended currently as a one-time dose for those 75 years+ and some 50–74-year-olds. Also, pregnancy indication for one product ONLY

Questions and contact info

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